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5 510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Diane Peterson Project Manager, Regulatory Affairs
Date Prepared:	December 21, 2005
Trade name:	PreSep Oximetry and PediaSat Oximetry Catheters *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor
Classification Name:	Catheter, Oximeter, Fiberoptic (21 CFR 870.1230) Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) Dilator, Vessel, For Percutaneous Catheterization (21 CFR 870.1310)
Predicate Devices:	Central Venous Oximetry Probe Catheter and Probe Multi-Med Multi-Lumen Central Venous Catheter Edslab Dual Lumen Regional Saturation Oximetry Catheter *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor SDM Percuglide
Device Description:	The PreSep Oximetry and PediaSat Oximetry Catheters are used with Edwards oximetry monitors to continuously measure oxygen saturation in adults and pediatrics. These catheters also provide the means for infusion of solutions, measuring pressure and taking blood samples. The dilator included with either the PreSep Oximetry or PediaSat Oximetry Catheter is used to enlarge the

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opening in a vessel for preparation of percutaneous entry of the catheter.

The *Vigileo* APCO/Oximetry monitor is a microprocessor-based instrument which, when connected to a dual disposable pressure transducer (DDPT), continuously measures arterial pressure cardiac output (APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry) in adults or pediatrics. The monitor also calculates other derived parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, system vascular resistance, and systemic vascular resistance index.

Intended Use:

The PreSep Oximetry and PediaSat Oximetry Catheters are intended to provide in adults and pediatrics the means for infusion of solutions, measuring pressure and taking blood samples through the distal, proximal and medial lumens. The PreSep Oximetry and PediaSat Oximetry Catheters also provide the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor.

The dilator included with either the PreSep Oximetry or PediaSat Oximetry Catheter is intended to be used in adults and pediatric patients for enlarging the opening in a vessel for preparation of percutaneous entry of the catheter.

The *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor is intended to measure arterial pressure cardiac output and oximetry. The monitor also calculates hemodynamic and oxygenation parameters. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics.

Comparative Analysis:

The PreSep Oximetry and PediaSat Oximetry Catheters, dilator and the *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor have been demonstrated to be as safe and effective as the predicate devices for their intended use.

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Functional/Safety Testing:	The PreSep Oximetry and PediaSat Oximetry Catheters, dilator and the *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor have successfully undergone functional testing. These products have been shown to be equivalent to the predicate devices.
Conclusion:	The PreSep Oximetry and PediaSat Oximetry Catheters, dilator and the *Vigileo* Arterial Pressure Cardiac Output/Oximetry Monitor are substantially equivalent to the predicate devices.

Edwards Lifesciences LLC
One Edwards Way · Irvine, CA USA · 92614

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Edwards Lifesciences LLC
c/o Ms. Diane Peterson
Project Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K053609
Trade Name: Vigileo APCO/Oximetry Monitor (MIHM1 & MIHM1P), PediaSat Oximetry Catheter Kit, and PreSep – Central Venous Oximetry Catheter Kit
Regulation Number: 21 CFR § 870.1230, 21 CFR § 870.1310, and 21 CFR §870.1435
Regulation Name: Fiberoptic Oximeter Catheter, Vessel Dilator for Percutaneous Vessel Dilation, and Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: II (two)
Product Code: DQE, DRE, and DXG
Dated: December 21, 2005
Received: December 27, 2005

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Edwards Lifesciences

4 Indications for Use Statement

510(k) Number (if known): K053609

Device Name: PreSep Oximetry Catheters
PediaSat Oximetry Catheters
Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor

Indications for Use:

The PreSep Oximetry and PediaSat Oximetry Catheters are indicated for hemodynamic monitoring in adults and pediatrics through blood sampling, pressure monitoring and oxygen saturation measurement.

The dilator, included with each catheter, is indicated for enlarging the opening in a vessel for preparation of percutaneous entry of the catheter.

The *Vigileo* Arterial Pressure Cardiac Output /Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
vision Sign-Off)
vision of Cardiovascular Devices
0(k) Number K053609

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